(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 893 096 A1

(12) **EUROPEAN PATENT APPLICATION**
published in accordance with Art. 158(3) EPC

(43) Date of publication:
27.01.1999 Bulletin 1999/04

(21) Application number: **97907411.9**

(22) Date of filing: **21.03.1997**

(51) Int. Cl.[6]: **A61B 17/00**, A61B 17/12

(86) International application number:
PCT/JP97/00930

(87) International publication number:
WO 98/29038 (09.07.1998 Gazette 1998/27)

(84) Designated Contracting States:
BE DE DK FR GB IT NL SE

(30) Priority: **27.12.1996 JP 349171/96**

(71) Applicant:
SUMITOMO BAKELITE COMPANY LIMITED
Tokyo 140 (JP)

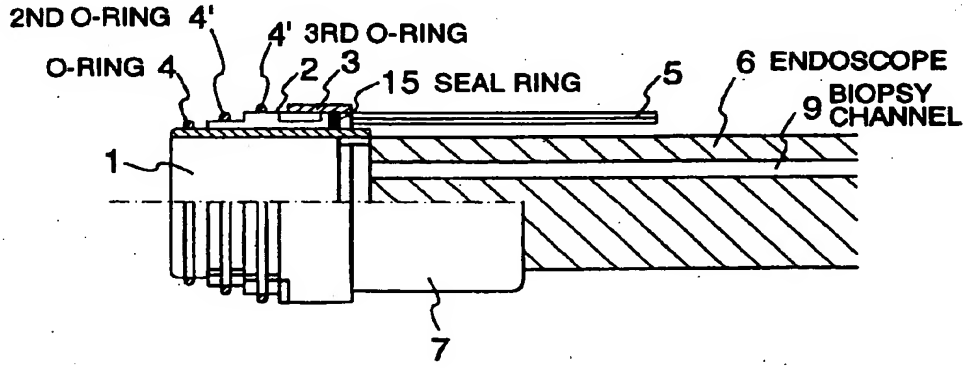
(72) Inventors:
- **SUZUKI, Zenetsu**
  Akita-shi Akita 010-01 (JP)
- **MASUDA, Haruhiko**
  Akita 010 (JP)

(74) Representative:
Vossius, Volker, Dr. et al
Dr. Volker Vossius,
Patentanwaltskanzlei - Rechtsanwaltskanzlei,
Holbeinstrasse 5
81679 München (DE)

(54) ENDOSCOPIC KIT FOR LIGATION

(57) There is disclosed an endoscopic ligation kit which is capable of successively effecting ligations safely and positively. This kit includes an inner cylinder, an outer cylinder having at least two bamboo shoot-like steps formed on an outer periphery of its distal end portion, and a slide cylinder provided between the inner cylinder and the outer cylinder. The outer cylinder has a notch extending from its distal end to its maximum outer diameter portion. On the other hand, the slide cylinder has at its distal end portion a projection which conforms in size to the notch, and has steps, and the projection is fitted in the notch. O-rings are mounted respectively on the outer periphery of the distal end portion of the inner cylinder and the step portions of the outer cylinder. When a fluid is fed into an annular hermetic space, formed at a rear side of the slide cylinder, to move the slide cylinder forwardly, the O-ring, mounted on the outer periphery of the distal end portion of the inner cylinder, is disengaged therefrom, and also the O-rings, mounted respectively on the step portions of the outer cylinder, are moved to the forwardly-adjacent step portions, respectively.

FIG.1B



EP 0 893 096 A1

Printed by Xerox (UK) Business Services
2.16.7/3.6

Description

TECHNICAL FIELD

This invention relates to one of the treatment methods for gastric and esophageal varices resulting from a liver disease. The invention relates to an endoscopic ligation kit used in a ligating operation in which a varix is ligated to thereby mechanically shut off a blood circulation so as to reduce, extinguish or thrombose the varix.

BACKGROUND ART

A mainstream treatment for gastric and esophageal varices due to liver cirrhosis or the like has heretofore been an endoscopic injection Sclerotherapy (EIS) in which an indurating agent, having a blood-coagulating nature, is injected into the varix or a portion outside the varix, and remains in this localized portion to shut off a blood circulation in the form of a thrombus, thereby devastating the varix, thus effecting the treatment.

However, the perivenous administration of the medicine, having side effects on the living body, has caused various complications, such as a pulmonary embolism, a pulmonary failure and a kidney disorder, in combination with complicated blood circulation kinetics of a portal hypertension. Therefore, a dose of the indurating agent is limited, and the treatment is carried out, taking the recovery of the patient into consideration, and therefore there has been encountered a problem that the treatment time is prolonged.

Recently, an esophageal varices ligation (EVL) has been used as a treatment method for gastric and esophageal varices. As shown in Fig. 3, EVL is a technique in which a varix 14 is drawn into a tubular device 11 mounted on a distal end of an endoscope 6, and an O-ring 4, beforehand expanded and fitted on an outer periphery of a cylinder 12, is disengaged from this cylinder by pulling the cylinder 12 through a wire inserted through a biopsy channel, and is fitted on a proximal end portion of the varix 14 drawn into a polyp-like shape, and the varix is mechanically ligated by a contracting force of rubber of the O-ring, thereby devastating the varix.

A currently-used ligation kit will now be described with reference to the drawings. Fig. 2B shows the construction of a ligation kit now extensively used, and a tubular device 11, mounted on a distal end of an endoscope 6, comprises an endoscope mounting portion 7, an outer tube 3, and a cylinder 12 having an O-ring 4 mounted on a distal end portion thereof. A wire 13, passed through the biopsy channel 9 in the endoscope, is beforehand connected to the cylinder 12, and when the wire 13 is pulled, the cylinder 12 is retracted, so that the O-ring 4 is pushed by the outer tube, and is disengaged from the cylinder 12.

Fig. 2A shows a pneumatically-driven ligation kit having a principle different from that of Fig. 2B. In this method, a slide cylinder 2 is provided between an inner cylinder 1 and an outer cylinder 3, and a fluid is fed under pressure from a syringe 10 via a connector 8 and a tract tube 5, and causes the slide cylinder 2 to be projected so as to disengage the O-ring 4, thereby ligating a varix. In the EVL using such an endoscopic ligation kit, it is not necessary to use a large amount of an indurating agent as in the conventional EIS, and this is a highly-safe treatment method having little side effects on the patient, and besides any particularly difficult technique is not required when effecting the treatment, and the ligating treatment can be carried out safely with a simple operation, and therefore the number of facilities, adopting this treatment method, has now been abruptly increasing.

However, in either of the devices, the endoscope must be withdrawn each time one ligation is effected, and then the O-ring must be set in position, and therefore much time has been required for inserting and withdrawing the endoscope.

A guide tube is kept in the pharynx so as to facilitate the insertion and withdrawal of the endoscope, and when withdrawing the endoscope after the ligation, the device, mounted on the distal end of the endoscope, is, in some cases, caught by a distal end of the guide tube, and is disengaged from the endoscope. In this case, the device, remaining in the body, is withdrawn by inserting a withdrawing forceps through the biopsy channel in the endoscope, and during this time, the treatment is interrupted. And, when inserting the guide tube, the mucosa is, in some cases, damaged by the distal end of the guide tube, and the type of device, which is capable of successively effecting ligations, and does not use a guide tube, has been desired in the market.

DISCLOSURE OF THE INVENTION

In order to overcome the problem of the conventional endoscopic ligation kits that the endoscope must be withdrawn each time one ligation is effected, and then the O-ring must be attached, the present invention have been studied in various ways, and an object thereof is to provide an endoscopic ligation kit which is capable of successively effecting ligations safely and positively.

There is provided an endoscopic ligation kit for attachment to a distal end of an endoscope so as to draw and ligate a tissue in a body cavity, such as gastric and esophageal varices, CHARACTERIZED in that the kit comprises an inner cylinder which has a rib at an outer periphery of its rear end portion, an outer cylinder which has at least two bamboo shoot-like steps formed on an outer periphery of its distal end portion and has at least one notch extending from its distal end to its maximum outer diameter portion, and a slide cylinder which has at least one projection at its distal end portion and has a seal ring fixedly secured to its rear end portion, the projection conforms in size to the notch in the outer

cylinder and has steps, the slide cylinder is received in the outer cylinder in such a manner that the projection of the slide cylinder is fitted in the notch in the outer cylinder, the inner cylinder is inserted into a bore of the slide cylinder, so that the outer cylinder and the inner cylinder are integrally connected together through the rib of the inner cylinder, this assembly is mounted on a distal end of a mounting tube and O-rings are mounted respectively on the outer periphery of the distal end portion of the inner cylinder and the step portions of the outer cylinder, an annular hermetic space is formed at a rear side of the seal ring by the seal ring, fixedly secured to the rear end of the slide cylinder, the outer cylinder and the inner cylinder, and the projection, formed on the slide cylinder, is projected forwardly by a fluid, inserted through a tube connected to a small hole in a rear end of the annular hermetic space, and disengages the O-ring, mounted on the outer periphery of the distal end portion of the inner cylinder, therefrom, and also moves the O-rings, mounted respectively on the step portions of the outer cylinder, to the forwardly-adjacent step portions, respectively.

In the above endoscopic ligation kit, a spring is provided on a distal end side of a space in which the slide cylinder can slide, and the slide cylinder, after projected, is returned by the spring.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a perspective view of a ligation kit used in the present invention, which view shows a condition in which O-rings are not mounted;

Fig. 1B is a cross-sectional view taken along the line A-A' of Fig. 1A, showing a condition in which an endoscope is attached to the kit of Fig. 1A;

Figs. 2A and 2B are views showing conventional endoscopic ligation kits, respectively; and

Fig. 3 is a view showing the manner of using an endoscopic ligation kit.

BEST MODE FOR CARRYING OUT THE INVENTION

The present invention will now be described in detail with reference to the drawings. Figs. 1A and 1B are views showing one embodiment of a ligation kit of the present invention, and Fig. 1A is a perspective view showing a condition in which O-rings are not mounted, and Fig. 1B is a cross-sectional view taken along the line A-A' of Fig. 1A, showing a condition in which the kit is attached to an endoscope. As shown in Fig. 1B, the ligation kit of the present invention comprises an inner cylinder 1 which forms a hood for drawing a varix by suction, and has a rib at its rear end, an outer cylinder 3 which has at least two bamboo shoot-like steps formed on its outer periphery, and has a notch extending from its distal end to its maximum outer diameter portion, and a slide cylinder 2 which has at its distal end portion a projection (which conforms in size to the notch in the outer cylinder 3, and has steps), and has a seal ring 15 fixedly secured to its rear end portion. As shown in Fig. 1A, the slide cylinder 2 is received in the outer cylinder 3 in such a manner that the projection of the slide cylinder 2 is fitted in the notch in the outer cylinder 3, and the inner cylinder 1 is inserted into the bore of the slide cylinder, so that the outer cylinder 3 and the inner cylinder 1 are integrally connected together through the rib of the inner cylinder, and this assembly is fixed to a distal end of a mounting tube 7. Further, an air-tight annular space is formed at the rear side of the seal ring 15 by the seal ring, fixedly secured to the rear end of the slide cylinder 2, the outer cylinder 3 and the inner cylinder 1, and a tract tube S for feeding a fluid is connected to a rear end of this annular space, and a syringe 10 is connected to a rear end of this tract tube, and a connector 8 for injecting the fluid is provided.

An O-ring is mounted on the outer periphery of the distal end portion of the inner cylinder 1, and also second and third O-rings are mounted respectively on the step portions of the outer cylinder 3, and the fluid is fed through the tract tube 5 into the annular hermetic space to slide the slide cylinder 2 forwardly, so that the projection, formed on the slide cylinder, is projected forwardly, and disengages the O-ring 4, mounted on the outer periphery of the distal end portion of the inner cylinder, therefrom, and also moves the second and third O-rings 4', mounted respectively on the step portions of the outer cylinder, to the forwardly-adjacent step portions, respectively. Then, the fluid is drawn by the syringe 10, so that the slide cylinder is returned to the condition before it is projected, and the next ligation can be effected. It is suitable that in order to return the slide cylinder to the condition before it is projected, a spring is provided in the annular hermetic space between the slide cylinder 2 and the outer cylinder 3.

That portion of the rear end of the slide cylinder 2 (fitted in the notched portion in the outer cylinder), to which the seal ring 15 is fixedly secured, has a ring-like shape, and the slide cylinder has at its distal end portion the projection which conforms in size to the notched portion in the outer cylinder, and has the steps, as shown in Fig. 1A. Therefore, the length of sliding of the seal ring 15 is determined by the annular hermetic space formed at the rear end portion of the outer cylinder 3.

On the other hand, with respect to the notched portion, in order to positively move the O-rings, the number of the notch in the outer cylinder is equal to the number of the projection on the slide cylinder, and the notch is provided in at least one portion. Preferably, the notches are provided at two portions, respectively, and for example, if the notches are provided on a diagonal line, that is, spaced 180 degrees from each other, the O-rings can be pressed uniformly, and can be moved smoothly. More preferably, the notches are provided at three or more portions, respectively, and when the number of the steps of the outer cylinder is increased so that the

number of the O-rings to be mounted thereon can be increased, a larger force is required for pressing the O-rings, and therefore if the number of the portions, at which the O-rings are pressed, is increased, the O-rings can be positively moved.

In Fig. 1B, although the three O-rings are mounted, the present invention is not limited to this, and the number of the O-rings can be increased, for example, to 4 or 5 by increasing the number of the bamboo shoot-like steps.

When the ligation kit of the present invention is to be used, the mounting tube 7 is fitted on the distal end of the endoscope 6, and is fixed thereto, and requirements for the mounting tube 7 are that it will not be easily disengaged from the endoscope and that it will not easily leak the air when a varix is drawn under a negative pressure. However, if the fitting of the mounting tube on the endoscope is too tight, this is liable to become the cause of a malfunction of the endoscope, and therefore it is preferred that the mounting tube should be made of a material having an appropriate degree of flexibility and sealing properties. The material is not particularly limited in so far as these conditions are satisfied, and for example, a flexible plastics material and rubber are particularly suitable.

The material for the common ligating O-rings, used in this kit, is not particularly limited in so far as it has sufficient elasticity to enable the ligation of a varix, and has no problem from the viewpoint of the safety, and for example, natural rubber and isoprene rubber and so on are suitable.

The inner cylinder 1, the outer cylinder 3 and the slide cylinder 2 are required to have a small thickness, a suitable degree of mechanical strength and high dimensional accuracies, and therefore a rigid resin is suitable, and further in order to enhance the operability, they are required to be transparent. The material is not particularly limited in so far as these conditions are satisfied, and examples thereof include polycarbonate resin, a polyvinyl chloride resin, a polysulfone resin, an acrylic resin and an ABS resin.

The seal ring 15, used in the present invention, need to be made of such a material that it keeps the annular hermetic space, and has good sliding properties. In order that the slide cylinder, after projected forwardly, can be returned by drawing the fluid, the slide cylinder and the seal ring must be integrally connected together. If the seal ring is not fixed, there is encountered a disadvantage that the slide cylinder, after projected, can not be returned, but only the seal ring 15 is returned, and this is not desirable. Therefore, the seal ring 15 need to be made of a material which can be easily bonded to the slide cylinder, or a material which can be easily formed into required dimensional accuracies so that the disengagement of the seal ring can be prevented by the fitting between convex and concave portions. As such a material, for example, rubber, such as silicone rubber and isoprene rubber, and a flexible plastics material are suitable, but the present invention is not particularly limited to these materials.

The tube, connected to the ligation device, need to be made of such a material that it is flexible, and will not be twisted and bent when operating the endoscope. As such a material, for example, silicone rubber, flexible vinyl chloride, a polyurethane resin, natural rubber and so on are suitable, but the present invention is not particularly limited to these materials.

In order to more clarify the effects of the present invention, a method of using the endoscopic ligation kit of the present invention will now be described. First, the ligation kit of the present invention is attached to a distal end of the endoscope 6, and the tract tube 5 is fixed to the endoscope 6 by a tape or the like. Then, xylocaine jelly or the like is coated on the outer surface of the endoscope, and it is inserted through a mouthpiece fixedly held in the mouth of the patient. Then, the distal end of the ligation kit is held against that part to be ligated in such a manner that this part can be directly viewed as much as possible, and a varix is drawn into the hood by a suction device incorporated in the endoscope. At this time, when it can be confirmed that the drawn varix becomes full in a visual field of the endoscope, the fluid is fed from the syringe to disengage the O-ring, thereby ligating the varix. Then, the fluid is drawn by the syringe 10, thereby returning the slide cylinder 2 to the condition before it is projected, and the next ligation is effected.

INDUSTRIAL APPLICABILITY

With respect to the problem that the conventional kit can not effect the ligations successively in a body cavity, the ligations can be successively effected easily and positively with the use of the endoscopic ligation kit of the present invention, and the treatment can be carried out without the use of a guide tube, and the treatment could be effected without damaging the mucosa by the guide tube. Particularly in the event of an emergency involving the bleeding, which requires a treatment even a second earlier, the rapid and positive treatment can be effected.

Claims

1. An endoscopic ligation kit for attachment to a distal end of an endoscope so as to draw and ligate a tissue in a body cavity, such as gastric and esophageal varices, CHARACTERIZED in that the kit comprises an inner cylinder which has a rib at an outer periphery of its rear end portion, an outer cylinder which has at least two bamboo shoot-like steps formed on an outer periphery of its distal end portion and has at least one notch extending from its distal end to its maximum outer diameter portion, and a slide cylinder which has at least one projection at its distal end portion and has a seal ring fix-

edly secured to its rear end portion, and the projection conforms in size to the notch in the outer cylinder, and has steps, the slide cylinder is received in the outer cylinder in such a manner that the projection of the slide cylinder is fitted in the notch in the outer cylinder, the inner cylinder is inserted into a bore of the slide cylinder, so that the outer cylinder and the inner cylinder are integrally connected together through the rib of the inner cylinder, this assembly is mounted on a distal end of a mounting tube and O-rings are mounted respectively on the outer periphery of the distal end portion of the inner cylinder and the step portions of the outer cylinder, an annular hermetic space is formed at a rear side of the seal ring by the seal ring, fixedly secured to the rear end of the slide cylinder, the outer cylinder and the inner cylinder, and the projection, formed on the slide cylinder, is projected forwardly by a fluid, inserted through a tube connected to a small hole in a rear end of the annular hermetic space, and disengages the O-ring, mounted on the outer periphery of the distal end portion of the inner cylinder, therefrom, and also moves the O-rings, mounted respectively on the step portions of the outer cylinder, to the forwardly-adjacent step portions, respectively.

2. An endoscopic ligation kit according to claim 1, in which a spring is provided on a distal end side of a space in which the slide cylinder can slide, and the slide cylinder, after projected, is returned by the spring.

FIG.1A

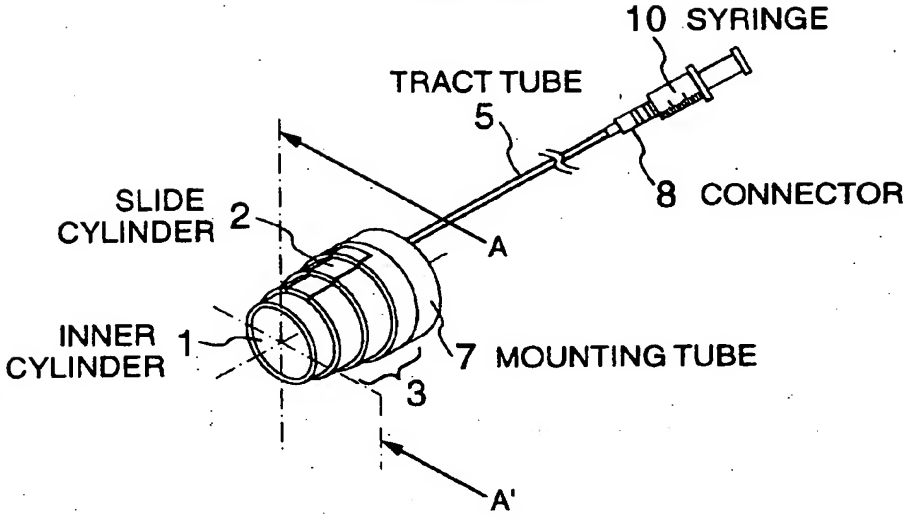

10 SYRINGE
TRACT TUBE
5
8 CONNECTOR
SLIDE CYLINDER 2
A
INNER CYLINDER 1
7 MOUNTING TUBE
3
A'

FIG.1B

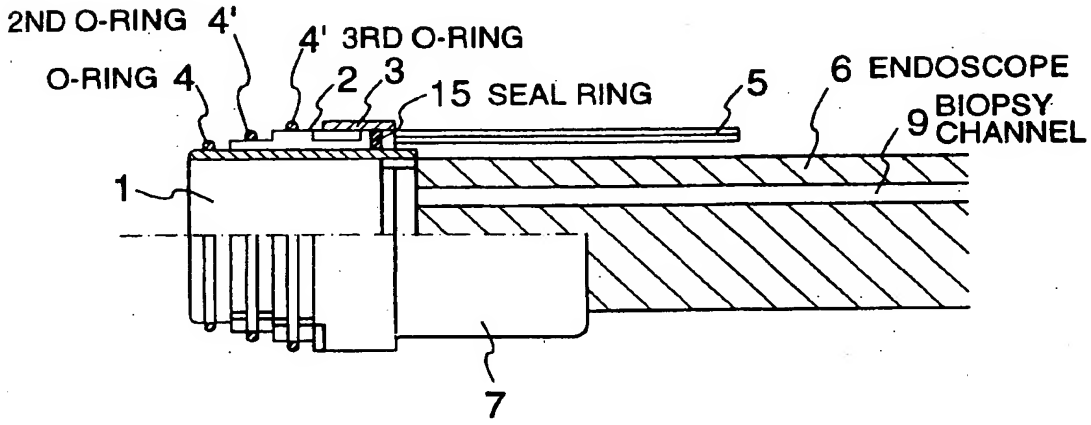

2ND O-RING 4'
4' 3RD O-RING
O-RING 4
2
3
15 SEAL RING
5
6 ENDOSCOPE
9 BIOPSY CHANNEL
1
7

FIG.2A

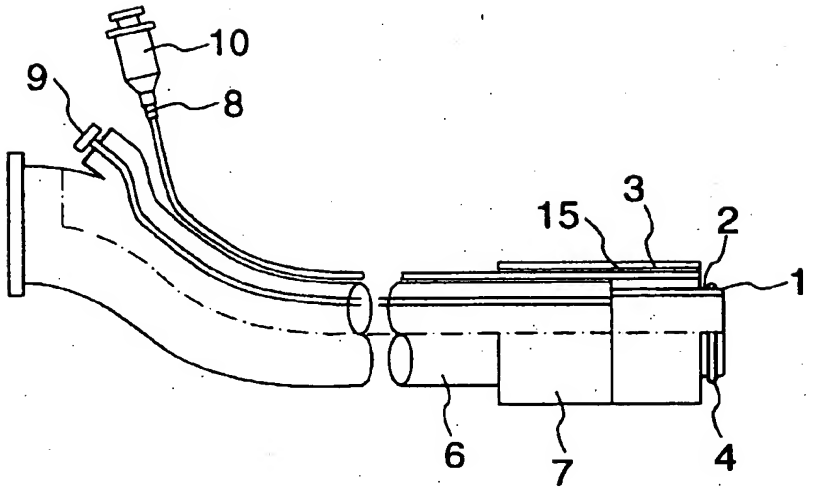


FIG.2B

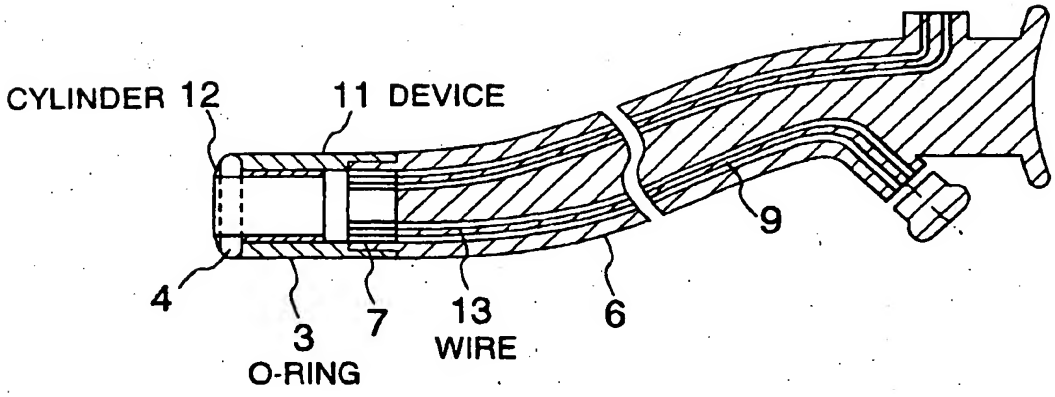
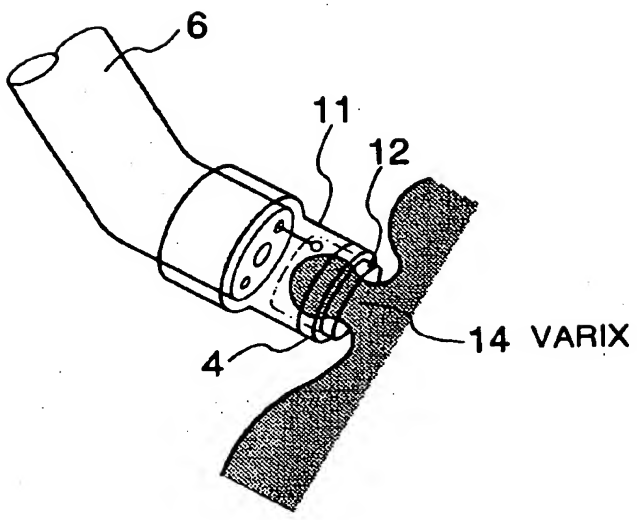


FIG.3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP97/00930

A. CLASSIFICATION OF SUBJECT MATTER
Int. Cl^6 A61B17/00, 17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int. Cl^6 A61B17/00, 17/12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1926 - 1997
Kokai Jitsuyo Shinan Koho 1971 - 1997
Toroku Jitsuyo Shinan Koho 1994 - 1997

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP, 8-10217, A (Top Corp.), January 16, 1996 (16. 01. 96) & US, 5569268	1 - 2
A	JP, 7-255733, A (Kazuhiko Yamaki), October 9, 1995 (09. 10. 95)(Family: none)	1 - 2
A	JP, 7-59786, A (Sumitomo Bakelite Co., Ltd.), March 7, 1995 (07. 03. 95)(Family: none)	1 - 2
A	JP, 53-38185, A (KLI, Inc.), April 7, 1978 (07. 04. 78) & US, 4226239	1 - 2

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
May 22, 1997 (22. 05. 97)	June 3, 1997 (03. 06. 97)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)